May 18, 2022

Lumenis Be, Ltd.
Shlomit Segman
Senior Director, RA
6 Hakidma Street PO BOX 240
Yokneam, Yokneam 2069204
Israel

Re: K220467
Trade/Device Name: The Family of UltraPulse CO2 Surgical and Aesthetic Lasers, Delivery Devices and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 17, 2022
Received: February 17, 2022

Dear Shlomit Segman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya, D.Eng.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220467

Device Name

The UltraPulse Alpha CO2 Surgical and Aesthetic Laser, Delivery Devices and Accessories

Indications for Use *(Describe)*

The UltraPulse Alpha CO2 Laser System, Delivery Devices and Accessories (members of the UltraPulse CO2 Laser Systems Family) are indicated for use in surgical or aesthetic applications requiring:
ablation, vaporization, excision, incision, or coagulation of soft tissue in medical specialties including: dermatology and plastic surgery (aesthetic), podiatry, , gynecology, general and thoracic surgery, dental and oral surgery and genitourinary surgery as follows:

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Laser derm-abrasion
- Laser burn debridement

-Laser skin resurfacing (ablation and/or vaporization) for treatment of:

- Wrinkles, rhytids, and furrows (including fine lines and texture irregularities).

-Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart and verruca seborrheica.
- Vermillionectomy of the lip
- Cutaneous horns
- Solar/actinic elastosis
- Cheilitis, including actinic cheilitis
- Lentigines, including lentigo maligna or Hutchinson’s malignant freckle
- Uneven pigmentation/dyschromia
- Acne scars
- Surgical scars
- Keloids including acne keloidalis nuchae
- Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum)
- Tattoos
- Telangiectasia
- Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
- Superficial pigmented lesions
- Adenosebaceous hypertrophy or sebaceous hyperplasia
- Rhinophyma reduction
- Cutaneous papilloma (skin tags)
- Milia
- Debridement of eczematous or infected skin
- Basal and squamous cell carcinoma, including keratoacanthomas, Bowen’s disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
- Nevi, including spider, epidermal and protruding
- Neurofibromas
- Laser de-epithelialization
- Tricoepitheliomas
- Xanthelasma palpebrarum

• Syringoma
-Laser ablation, vaporization and/or excision for complete and partial nail matrixectomy. Vaporization or coagulation of:
• Benign and malignant vascular/avascular skin lesions
• Moh's Surgery
• Lipectomy
• Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts
-Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.
-Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue for the reduction, removal, and/or treatment of:
• Verrucae vulgares/plantar (warts), including paronychial, periungal and subungual warts
• Porokeratoma ablation
• Ingrown nail treatment
• Neuromas/fibromas, including Morton’s neuroma
• Debridement of ulcers
• Other soft tissue lesions
Laser ablation, vaporization, and/or excision for complete and partial matrixectomy

Gynecology (GYN)
Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:
• vulvar and vaginal intraepithelial neoplasia (VIN, VAIN)
• Condyloma acuminata, including genital, vulvar, perineal, and Bowen’s disease (Erythrolasia of Queyrat) and Bowenoid papulosa (BP) lesions
• Leukoplakia (vulvar dystrophies)
• Incision and drainage (I&D) of Bartholin’s and nubuthian cysts
• Herpes vaporization
• Urethral caruncle vaporization
• Benign and malignant tumors
• Hemangiomas

General Surgery
• Debridement of traumatic wounds
• Debridement of decubitus and diabetic ulcers
• Microsurgery
• Artificial joint revision
• PMMA removal

General and Thoracic Surgery
Incision, excision and vaporization of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:
• Debridement of decubitus ulcers, stasis, diabetic, and other ulcers
• Mastectomy
• Debridement of burns
• Rectal and anal hemorrhoidectomy
• Breast biopsy
• Reduction mammoplasty
• Cytoreduction for metastatic disease
• Laparotomy applications
• Mediastinal and thoracic lesions and abnormalities
• Skin tag vaporization
• Atheroma
• Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips
• Pilonidal cyst removal and repair

- Abscesses
- Other soft tissue applications

Dental and Oral Surgery
Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:
- Gingivectomy/removal of hyperplasias
- Gingivoplasty
- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- Operculectomy
- Crown lengthening
- Removal of soft tissue, cysts and tumors
- Oral cavity tumors and hemangiomas
- Abscesses
- Extraction site hemostasis
- Salivary gland pathologies
- Preprosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

Genitourinary
Incision/excision and vaporization of soft tissue in genitourinary procedures. Applications include:
- Benign and malignant lesions of external genitalia
- Condyloma
- Phimosis
- Erythroplasia

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220467

Device Name

The UltraPulse SurgiTouch and UltraPulse Encore CO2 Surgical and Aesthetic Laser, Delivery Devices and Accessories

Indications for Use *(Describe)*

The UltraPulse SurgiTouch and UltraPulse Encore CO2 Laser System, Delivery Devices and Accessories (members of the UltraPulse CO2 Laser Systems Family) are indicated for use in surgical or aesthetic applications requiring: ablation, vaporization, excision, incision, or coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology (including laparoscopy), neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery as follows:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Laser derm-abrasion
- Laser burn debridement

Laser skin resurfacing (ablation and/or vaporization) for treatment of:

- Wrinkles, rhytids, and furrows (including fine lines and texture irregularities).

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- Keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart and verruca seborrheica.
- Vermillionectomy of the lip
- Cutaneous horns
- Solar/actinic elastosis
- Cheilitis, including actinic cheilitis
- Lentigines, including lentigo maligna or Hutchinson’s malignant freckle
- Uneven pigmentation/dyschromia
- Acne scars
- Surgical scars
- Keloids including acne keloidalis nuchae
- Hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum)
- Tattoos
- Telangiectasia
- Removal of small skin tumors, including periungual (Koenen) and subungual fibromas
- Superficial pigmented lesions
- Adenosebaceous hypertrophy or sebaceous hyperplasia
- Rhinophyma reduction
- Cutaneous papilloma (skin tags)
- Milia
- Debridement of eczematous or infected skin
- Basal and squamous cell carcinoma, including keratoacanthomas, Bowen’s disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions
- Nevi, including spider, epidermal and protruding
- Neurofibromas
- Laser de-epithelialization
- Tricoepitheliomas

- Xanthelasma palpebrarum
- Syringoma

Laser ablation, vaporization and/or excision for complete and partial nail matrixectomy.

Vaporization or coagulation of:

- Benign and malignant vascular/avascular skin lesions
- Moh's Surgery
- Lipectomy
- Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts

Laser incision and/or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and/or excision of soft tissue for the creation of recipient sites for hair transplantation

Podiatry

Laser ablation, vaporization, and/or excision of soft tissue for the reduction, removal, and/or treatment of:

- Verrucae vulgares/plantar (warts), including paronychial, periungal and subungual warts
- Porokeratoma ablation
- Ingrown nail treatment
- Neuromas/fibromas, including Morton’s neuroma
- Debridement of ulcers
- Other soft tissue lesions

Laser ablation, vaporization, and/or excision for complete and partial matrixectomy

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology for the treatment of:

- Choanal atresia
- Leukoplakia, including oral, larynx, uvula, palatal, and upper lateral pharyngeal tissue
- Nasal obstruction
- Adult and juvenile papillomatosis polyps
- Polypectomy of nose and nasal passages
- Lymphangioma removal
- Removal of vocal cord/fold nodules, polyps and cysts
- Removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords.
- Laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue
- Zenker’s Diverticulum/pharyngoesophageal diverticulum (endoscopic laser-assisted esophagodiverticulostomy (ELAED))
- Stenosis, including subglottic stenosis
- Tonsillectomy (including tonsillar cryptolysis and neoplasma) and tonsil ablation/tonsillotomy
- Pulmonary bronchial and tracheal lesion removal
- Benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial)
- Benign and malignant lesions and fibromas (nose and nasal passages)
- Benign and malignant tumors and fibromas (oral)
- Stapedotomy/Stapedectomy
- Acoustic neuroma in the ear
- Superficial lesions of the ear, including chondrodermatitis nondularis chronica helices/Winkler’s disease
- Telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal, or upper lateral pharyngeal tissue)
- Cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea
- Myringotomy/tympanostomy (tympanic membrane fenestration)
- Uvulopalatoplasty (LAUP, laser UPPP)
- Turbinectomy and turbinate reduction/ablation
- Septal spur ablation/reduction and septoplasty
- Partial glossectomy
- Tumor resection of oral, subfacial and neck tissues
- Rhinophyma
- Verrucae vulgares (warts)
- Gingivoplasty/gingivectomy

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of:

- Conization of the cervix, including cervical intraepithelial neoplasia (CIN), and vulvar and vaginal intraepithelial neoplasia (VIN, VAIN)
- Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease (Erythrolasia of Queyrat) and Bowenoid papulosa (BP) lesions
- Leukoplakia (vulvar dystrophies)
- Incision and drainage (I&D) of Bartholin's and nubuthian cysts
- Herpes vaporization
- Urethral caruncle vaporization
- Cervical dysplasia
- Benign and malignant tumors
- Hemangiomas

GYN Laparoscopy

Vaporization, incision, excision, ablation or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including gynecological laparoscopy, for the treatment of:

- Endometrial lesions, including ablation of endometriosis
- Excision/lysis adhesions
- Salpingostomy
- Oophorectomy/ovariectomy
- Fimbrioplasty
- Metroplasty
- Microsurgery (tubal)
- Uterine myomas and fibroids
- Ovarian fibromas and follicle cysts
- Uterosacral ligament ablation
- Hysterectomy

Neurosurgery

Laser incision, excision, ablation and/or vaporization of soft tissue in neurosurgery for the treatment of:

Cranial

- Posterior fossa tumors
- Peripheral neurectomy
- Benign and malignant tumors and cysts, for example, gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas, and large tumors
- Arteriovenous malformation
- Pituitary gland tumors (transphenoidal approach)

Spinal cord

- Incision/excision and vaporization of benign and malignant tumors and cysts
- Intra and extradural lesions
- Laminectomy/laminotomy/microdiscectomy

Orthopedic

Incision/excision and vaporization of soft tissue in orthopedic surgery, including the following applications:

- Arthroscopy
- Menisectomy
- Chondromalacia
- Chondroplasty
- Ligament release (lateral and other)
- Excision of plica
- Partial synovectomy

General

- Debridement of traumatic wounds
- Debridement of decubitus and diabetic ulcers
- Microsurgery

- Artificial joint revision
- PMMA removal

General and Thoracic Surgery

Incision, excision and vaporization of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- Debridement of decubitus ulcers, stasis, diabetic, and other ulcers
- Mastectomy
- Debridement of burns
- Rectal and anal hemorrhoidectomy
- Breast biopsy
- Reduction mammoplasty
- Cytoreduction for metastatic disease
- Laparotomy and laparoscopic applications
- Mediastinal and thoracic lesions and abnormalities
- Skin tag vaporization
- Atheroma
- Cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips
- Pilonidal cyst removal and repair
- Abscesses
- Other soft tissue applications

Dental and Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- Gingivectomy/removal of hyperplasias
- Gingivoplasty
- Incisional and excisional biopsy
- Treatment of ulcerous lesions, including aphthous ulcers
- Incision of infection when used with antibiotic therapy
- Frenectomy (frenum release)
- Excision and ablation of benign and malignant lesions
- Homeostasis
- Operculectomy
- Crown lengthening
- Removal of soft tissue, cysts and tumors
- Oral cavity tumors and hemangiomas
- Abscesses
- Extraction site hemostasis
- Salivary gland pathologies
- Preprosthetic gum preparation
- Leukoplakia
- Partial glossectomy
- Periodontal gum resection

Genitourinary

Incision/excision and vaporization of soft tissue in genitourinary procedures. Applications include:

- Benign and malignant lesions of external genitalia
- Condyloma
- Phimosis
- Erythroplasia

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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5. 510(K) SUMMARY

UltraPulse Family of CO_2 Laser System, Delivery Devices and Accessories

Applicant Name:	Lumenis Be Ltd. 6 Hakidma Street PO Box 240 Yokneam Industrial Park, Yokneam 2069204, Israel Tel: +972-4-9599000 Fax: +972-4-9599046
Contact Person:	Shlomit Segman, Lumenis Be Ltd. 6 Hakidma Street PO Box 240, Yokneam Industrial Park, Yokneam 2069204, Israel Tel: +972-4-9599230 Fax: +972-4-9599198 Email:Shlomit.Segman@lumenis.com

Date Prepared:	February 17th, 2022
Trade Name:	UltraPulse Family of CO_2 Surgical and Aesthetic Lasers, Delivery Devices and Accessories
Classification Name:	Powered laser surgical instrument
Product Code:	GEX
Device Class:	Class II
Regulation Number:	21 CFR 878.4810
Panel:	General & Plastic Surgery
Predicate Devices:	Primary: K203544 Lumenis Modified Family of UltraPulse CO2 Surgical and Aesthetic Laser Systems Reference: K030147 and K022060 Lumenis Be UltraPulse SurgiTouch and Encore CO_2 Lasers, Delivery Devices and Accessories.

Intended Use/ Indications for Use:

The indications for use for the subject devices are as attached (see FDA Indications for Use Forms 3881.)

Device Description

The Lumenis Be Family of UltraPulse CO_2 Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories (subject devices) consist of the following devices:

Laser Systems

- UltraPulse Alpha (also written as UltraPulse α)
- UltraPulse Encore
- UltraPulse SurgiTouch

Delivery Devices and Accessories

- DeepFX Microscanner and disposable tips
- UltraScan CPG Microscanner
- TrueSpot 2.0 mm Collimated Handpiece
- 0.2 mm and 1.0 mm Focused Incisional Handpieces (also called Standard Handpieces)

Each UltraPulse laser system is an advanced computer-controlled device with RF - modulated CO2 laser tube technology that emits laser beams at a wavelength of 10,600 or 11,100 nm. Each has an additional diode laser in the red visible spectrum emitting along the same optical path as the CO2 to serve as an aiming beam.

Attached to each laser system are the delivery devices and accessories that direct the laser beams to the intended treatment site in the format as selected by the user.

Substantial Equivalence Discussion

In comparison to the predicate Lumenis Family of UltraPulse CO_2 Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories (cleared under K203544), the subject Lumenis Be Family of UltraPulse CO_2 Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories share the identical technological characteristics, operating principles, and manufacturing process.

Only labeling changes are to be implemented with this 510(k). The key labeling change is to reflect the new name for the manufacturer, which is Lumenis Be. In addition, there will be labeling changes to reflect the UltraPulse α ("Alpha") unit that supports only a subset of the indications cleared for its predecessor, predicate UltraPulse Model, as well as additional clarifications and incorporating the individual instruction booklets for the accessories into the laser manual.

Summary of Testing

For the labeling changes described in the 510(k), no testing was required.

Conclusion

None of the identified labeling changes raises a new safety or effectiveness questions. The Lumenis Be Family of UltraPulse CO_2 Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories (subject devices) is substantially equivalent to the Lumenis Family of UltraPulse CO_2 Surgical and Aesthetic Laser Systems, Delivery Devices and Accessories (predicate devices).